

33) and oral dosage forms comprising particles (claims 34-38), classified in class 424, subclass 494.

Group III: Claims 39-41, drawn to methods of treating disorders by administering oral dosage forms according to claim 34, classified in class 514, subclass 1.

Additionally, the Examiner has required election of a single disclosed species for an active agent of claims 1-8, 13-23 and 28-41.

PROVISIONAL ELECTION

Applicants hereby provisionally elect claims 1-27 of Group I, drawn to a process of manufacturing an active agent oral dosage form (claims 1-22) and particles produced by the process (claims 23-27), with traverse.

To the election requirement, Applicants hereby provisionally elect a single disclosed species "ketoconazole" for an active agent, with traverse.

The elected species ketoconazole is an antifungal, as claimed in claim 8 and disclosed as such in the specification, on page 8, line 3. The claims that read upon the elected species are claims 1-8 and 15-23.

Applicants reserve the right to file a divisional application directed to the non-elected subject matter.

Further, Applicants note that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as

provided by 37 C.F.R. §1.141.

TRAVERSAL

Applicants respectfully traverse the Examiner's restriction/election requirement for the following reasons.

Applicants asserts that all claims of Groups I-III, claims 1-41, should be examined together because such examination would not present a "serious burden" under MPEP 803.

MPEP 803 specifies that restriction/election between two groups of claims is only proper when (1) one group of claims is independent or distinct from another group of claims **and** (2) a "serious burden" exists on the examiner in examining both groups of claims. If the search and examination of all the claims in one application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

The Examiner can show a "serious burden" by establishing one of: the inventions are classified separately; the inventions have been classified together, but it can be shown that each subject has formed a separate subject for inventive effort (can cite patents or show a separate field of search); or the inventions require a separate field of search, that is, it is necessary to search for one subject in a place where no pertinent art for the other subject exists (MPEP 808.02 (c)).

In the present application, the Examiner omits "an appropriate explanation" as to the existence of a "serious burden" if a restriction were not required among the claims

of Groups I-III. While the Examiner provides a long explanation in the Official Action as to why he alleges the inventions of Groups I-III are not related, being independent or distinctive one another, the Examiner, for the existence of serious burden, just alleges on page 3 of the Official Action that:

“[T]he inventions are independent and distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required. Because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purpose is proper”.

Assuming *arguendo* that the Examiner can establish the distinctiveness among the inventions of Groups I-III, the Examiner must still establish a “serious burden” resulting from examination of Groups I-III of claims, which he has failed to do.

In addition, the Examiner classifies, on page 2 of the Official Action, claims 1-27 of Group I in class 424, subclass 490, claims 28-38 of Group II in class 424, subclass 494 and claims 39-41 of Group III in class 514, subclass 1. However, combining all of these groups for examination in the present application would not present a *serious* burden.

Specifically, claims 1-27 are drawn to a method of manufacturing an active agent oral dosage form, which is finally formed from the active agent-coated particle prepared by the process described in claim 1, and to the same particle; and claims 28-38 are drawn to a pharmaceutically acceptable particle having an active agent-coated core and to an oral dosage form comprising said particle. Therefore, the method and the particle of Group I and the particle and the oral dosage form of Group II can be both classified in class 424, subclass 490 for the search.

In addition, claims 39-41 are drawn to a method of treating disorders by administering an oral dosage form of claim 34, in other words, a pharmaceutical use of the oral dosage form comprising the particle of claim 28. The particle of claim 28 comprises again an active-agent coated core. Therefore, the claims of Group III can also be classified in the same class 424, subclass 490 for the search, or at least it would be necessary to concurrently search the art in class 424, subclass 490 since the distinctive technical feature of the claims of Group III is ultimately in the use of the particle of claim 28. Consequently, a "serious burden" would not exist on the examiner in examining all the claims of Groups I-III.

Further, a complete and thorough search for the invention set forth in an alleged Group would require searching the art areas appropriate to the other Groups. Since a search of each of the inventions of Groups I-III would be coextensive, it would not be a *serious* burden upon the Examiner to examine all of the claims in this application. Further, at the Examiner's disposal are powerful electronic search engines providing the Examiner with the ability to quickly and easily search all the claims.

Furthermore, Applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when filing this application and persists in requiring Applicants to file divisional applications for each of the groups of claims, the Examiner would essentially be forcing applicants to pay duplicative fees for the non-elected or withdrawn claims, inasmuch as the original filing fees for the claims (which would be later prosecuted in divisional applications) are not refundable.

Accordingly, Applicants respectfully request that the restriction requirement be withdrawn.

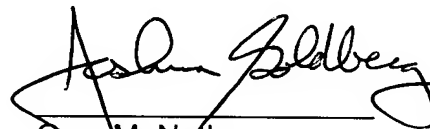
CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement and the election of species requirement, and to examine all claims 1-41 pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

THE NATH LAW GROUP

A handwritten signature in black ink, appearing to read "Gary M. Nath", written over a horizontal line.

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